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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/358,321 | 07/21/1999 | KITISRI SUKHAPINDA | 50.447 | 1398 |

25212 7590 06/03/2003

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| EXAMINER |
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COLLINS, CYNTHIA E

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| ART UNIT | PAPER NUMBER |
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1638

23

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/358,321

Applicant(s)

SUKHAPINDA ET AL.

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,9,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1638

DETAILED ACTION

The Amendment filed March 4, 2003, paper no. 22, has been entered.

Claims 7 and 10 are cancelled.

Claims 1, 5, 8 and 13 are newly amended.

Claims 1-6, 8-9 and 12-13 are pending and are examined in the instant office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-6, 8-9 and 12-13 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule of SEQ ID NO:31 encoding a single-chain Fv antibody having the amino acid sequence of SEQ ID NO:32, and a method of decreasing the steady state level of maize stearyl-ACP Δ -9 desaturase in maize cells by expressing the nucleic acid molecule of SEQ ID NO:31, does not reasonably provide enablement for a method of decreasing the steady state level of a passenger protein in a plant cell by expressing the nucleic acid molecule of SEQ ID NO:31, for the reasons of record set forth in the office action mailed October 22, 2002.

Applicants' arguments filed March 4, 2003, have been fully considered but they are not persuasive.

Art Unit: 1638

Applicants argue that the amendment of claim 1, and all subsequent claims, to limit the scope of the nucleic acids coding for the necessary anti-transit antibody to a single nucleic acid of SEQ ID NO:31 should overcome the rejection (reply page 4).

While the amendment of claim 1 to limit the scope of the nucleic acids coding for the necessary anti-transit antibody to a single nucleic acid of SEQ ID NO:31 adequately addresses the unpredictability of which anti-transit antibody encoding nucleic acid to express for the purpose of decreasing the steady state level of maize stearoyl-ACP Δ -9 desaturase, the amendment does not fully address the issue of the unpredictability of decreasing the steady state level of the polypeptide it binds. The claims are still directed to decreasing the steady state level of a "passenger" protein. As was stated at page 4 of the Office Action mailed January 18, 2002, the ability of an ectopically expressed single-chain Fv antibody to decrease the steady state level of the polypeptide it binds is unpredictable. The specification does not provide sufficient guidance for one skilled in the art to determine which "passenger" proteins may be downregulated using the claimed method, and which may not, because the specification discloses only a single passenger protein whose steady state level is decreased using the claimed method, maize stearoyl-ACP Δ -9 desaturase. That any protein may be engineered to contain the maize stearoyl-ACP Δ -9 desaturase transit peptide is not germane, as the ability of an antibody to both bind to a transit peptide and to decrease the steady state level of the transit peptide's cognate protein is unpredictable. Binding is not the same as neutralizing and does not automatically downregulate a specific activity or function (see page 4 of the Office Action mailed October 22, 2002).

Art Unit: 1638

Newly amended claims 5 and 13 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "derived", for the reasons of record set forth in the office action mailed October 22, 2002.

Applicants' arguments filed March 4, 2003, have been fully considered but they are not persuasive.

Applicants argue that the amendment of claims 5 and 13 to recite that the plant or progeny contain a functional single chain Fv described by SEQ ID NO:32 should overcome the rejection, as this limits the claims to plants and progeny which possess the recombinant phenotype (reply page 5).

While the amended claims are limited to plants or progeny that contain a functional single chain Fv described by SEQ ID NO:32, it is still unclear what aspects of the plant cells of claims 2 and 12 would be retained by a "derived" product. It is also unclear what a plant or progeny "derived" from the plant cell of claim 2 or 12 would contain, only the functional single chain Fv described by SEQ ID NO:32, or the nucleic acid encoding the functional single chain Fv described by SEQ ID NO:32 as well? It is suggested that the claims be amended to recite that the plants or progeny thereof are "obtained" from the plant cell of claim 2 rather than "derived" from the plant cell of claim 2 in order to overcome the rejection.

Newly amended claims 5 and 13, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1638

Claims 5 and 13 are indefinite in the recitation of "a functional single chain Fv described by SEQ ID NO:32". It is unclear what aspects of SEQ ID NO:32 would be possessed by a functional single chain Fv "described" by SEQ ID NO:32. Would the functional single chain Fv described by SEQ ID NO:32 have the amino acid sequence set forth in SEQ ID NO:32? Would the functional single chain Fv described by SEQ ID NO:32 have a certain percent homology or similarity to the amino acid sequence set forth in SEQ ID NO:32?

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Art Unit: 1638

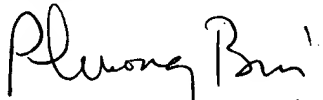
Claims 1-6, 8-9 and 12-13 are deemed free of the prior art, due to the failure of the prior art to teach or suggest a nucleic acid molecule of SEQ ID NO:31 encoding the amino acid sequence of SEQ ID NO:32.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
May 26, 2003


PHUONG T. BUI
PRIMARY EXAMINER 6/2/03